K071283

510(k) Summary

JUN - 1 2007

1.0 Submitted By:

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Brea, CA 92822-8000
Telephone: (714) 961-3626
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2.0 Date Submitted

May 4, 2007

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON® Systems Creatinine Reagent

3.2 Classification Names

Creatinine test system (21 CFR § 862.1225)

4.0 Legally Marketed Device

The SYNCHRON Systems Creatinine (CR-S) Reagent claims substantial equivalence to the Beckman Coulter SYNCHRON Systems Creatinine (CREA) reagent currently in commercial distribution, FDA 510(k) Number K042291.

5.0 Device Description

The SYNCHRON Systems CR-S Reagent is designed for optimal performance on the SYNCHRON UniCel DxC (UniCel DxC 600, DxC 800, UniCel DxC 600i) Systems. The reagent kit contains two 300-test cartridges, and is packaged separately from the associated calibrators.

6.0 Intended Use

CR-S reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of Creatinine concentration in human serum, plasma or urine.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The modification to the SYNCHRON Systems CREA assay involves duplication of the system parameters under the acronym CR-S. The calibration methodology will be modified from a single point linear method with a fixed intercept using CX Multical (serum matrix) to a two point linear calibration using AQUA CAL on 1 and 2 (aqueous matrix) on UniCel DxC systems. Values assigned to the calibrator material are traceable to Isotope Dilution Mass Spectometry (IDMS) for creatinine recovery.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Beckman Coulter, Inc.
c/o Ms. Tara M. Viviani,
Senior Regulatory Affairs Specialist
200 South Kraemer Blvd., M/S W-110
Brea, CA 92821

JUN - 1 2007

Re: k071283
Trade/Device Name: Synchron® Systems Creatinine Reagent
Regulation Number: 21 CFR§ 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: CGX
Dated: May 04, 2007
Received: May 07, 2007

Dear Ms. Viviani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071283

Device Name: **SYNCHRON® Systems Creatinine Reagent**

Indications for Use:

CR-S reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of creatinine concentration in human serum, plasma or urine.

Clinical Significance:

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use ✓ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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